## REMARKS

Applicant has carefully studied the non-final Examiner's Action mailed October 18, 2004. The amendment appearing above and these explanatory remarks are believed to be fully responsive to the Action. Accordingly, this important patent application is now believed to be in condition for allowance.

Applicant responds to the outstanding Action by centered headings that correspond to the centered headings employed by the Office, to ensure full response on the merits to each finding of the Office.

### Specification

The traditional numbering system in the related application has been replaced due the electronic filing of the subject application. The software, required by the USPTO, places indicators such as [c1] for claim 1 in place of the Arabic indicator found on paper filings. Accordingly, the grounds for the objection is a function of the electronic filing system and cannot be corrected by Applicant.

### Claim Objections

Claims 9 and 10 stand objected to under 37 C.F.R. 1.75 as being substantial duplicates of claims 1-4 and 5-8. Applicant respectfully traverses this objection on the grounds that that claims 9 and 10 restate the invention in a scope different from claim 1-4 and 5-8.

MPEP §706.03(k) states that "court decisions have confirmed an applicant's right to restate (i.e. by plural claiming) the invention in a reasonable number of ways. Indeed, a mere difference in scope between claims has been held to be enough." The same section states that "when *two* claims in an application are duplicates ... it is proper after *allowing one claim* to object to the other claim under 37 C.F.R. 1.75 as being a substantial duplicate of the allowed claimed." (emphasis added)

Here, claims 9 and 10 are not duplicates of any other single claim. Combining claim sets to achieve a duplicate embodiment of a single claim is improper under this section. Furthermore, no claims have been allowed and therefore the objection is improper.

**35 U.S.C. §112, first paragraph**

Claims 1-10 stand rejected under 35 U.S.C. §112, first paragraph because the specification does not reasonably provide enablement for inhibiting the growth of other types of cancer cells. Applicant respectfully traverses this rejection on the grounds that the office as not established a *prima facie* case of lack of enablement.

Per MPEP §2164.01(a) there are a multitude of factors to be considered when determining if there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement. The test of enablement is whether experimentation needed to practice an invention is undue or unreasonable.[1]

In *In re Wands*,[2] the court reversed a rejection based on lack of enablement under 35 U.S.C. §112, first paragraph, finding that no undue experimentation would be necessary to practice the claimed invention. The court found that the specification provided information on how to *practice* the invention. Given that the level of skill in the art, biotechnology, was high the methods needed to practice the method were known. The court also noted that the applicant carried out experiments for making the invention and was successful in producing at least one antibody which fell within the scope of the claims. The court did not limit the scope of the claims to the particular antibodies established.

Furthermore, it has been held that nothing more than objective enablement is required in the patent specification; it is irrelevant whether the teaching is provided through broad terminology or illustrative examples.[3] Although working examples are beneficial in complex technologies and working examples can satisfy the enablement requirement, examples are not required to satisfy the adequate disclosure requirement of §112.[4] Moreover, compliance with 35 USC 112, first paragraph does not turn on whether an example is disclosed. The mere fact that something has not previously been

[1] See MPEP §2164.01, citing *Mineral Seperation v. Hyde*, 242 U.S. 261, 270 (1916).
[2] In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).
[3] *Fonar Corp. v. General Elec. Co.*. E.D.N.Y. 1995, F.Supp. 330, 41 USPQ2d 1088.
[4] *Lawson v. Bruce*, 222 F.2d 273, 42 CCPA 893 (1955), 105 USPQ 440.

done clearly is not, in itself, a sufficient basis for rejecting all applications purporting how to disclose how to practice it.[5]

The presence of one working example should never be the sole reason for rejecting claims as being broader than the enabling disclosure.[6] A valid rejection requires an evaluation of why one skilled in the art would not expect to be able to use the invention across the entire scope of the claims.

The Office has coupled the use of only example, pancreatic carcinoma, with a teaching by Weigle et al.[7] that certain small cell lung cancer lines, OS-A and SHP-77, secrete ANP (which is used in the invention to treat cancer) to support the rejection. The Office then deduced that since certain types of cancer cell lines secrete the inhibitory agent of the disclosure that the agent would be ineffective to treat that type of cancer. Although the Office's assessment of teaching of Weigle et al. is accurate, the teaching does not speak to the dose of ANP stably produced by the cell line. Thus, although Weigle et al. have shown small-cell lung cancer cells do make ANP, they have not established that the cells produce ANP in sufficient quantities to prevent the cells from proliferating.

Consider, by analogy, the treatment of insulin-requiring type 2 diabetics. Type 2 diabetics (roughly 85% of all diabetics) make normal or even increased amounts of insulin, yet the insulin they create is insufficient to control their blood glucose levels. The addition of exogenous insulin (an effective amount) then brings their blood glucose levels under control. This same concept applies here; although small-cell lung cancer SHP-77 can make ANP, if one gives more of the four peptide hormones (particularly vessel dilator) then the anti-cancer effects become manifest.

It cannot be said, in light of W*ands*, that it would require undue experimentation, given the level of skill in the art, to apply the teachings of the present invention to different cell lines. Nor can it be said that simply increasing the dosage of a given compound is unreasonable. The specification need not contain an example identical to the scope of the claims if the invention is otherwise disclosed in such a manner that one skilled in the art would be able to practice the invention without an undue amount of

[5] MPEP 2164.02, citing *Ghould v. Quigg,* 822 F.2d 1074, 1078, 3 USPQ2d 1302, 1304 (Fed. Cir. 1987).
[6] MPEP 2164.02

experimentation.[8] Here, the only experimentation that would be required is the application of the inventive method, which is clearly delineated in the specification, against the cell line of interest with adjustments in dosage to achieve the desired result.[9]

Finally, and in support of the enabling character of the original specification, Applicant hereby submits the inventor's Rule 132 Declaration, attached hereto, demonstrating similar results using substantially the same protocol used in the original application. A plain reading of the supporting information makes it cleat that the minor variations in protocol cannot be said to be undue experimentation.

**35 USC §112, second paragraph**

Claims 1, 4-5, and 8-10 stand rejected under 35 USC 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicant respectfully traverses this rejection on the grounds that the rejection, as made, is improper.

MPEP §2172 states:

> a rejection based on the failure to satisfy this requirement is appropriate *only* where the applicant has stated, *somewhere other than the in the application as filed*,[10] that the invention is something different from what is defined in the claims. The invention set forth in the claims must be presumed, in the absence of evidence to the contrary, to be that which applicant regards as their invention.[11] (emphasis added)

Applicant has filed no papers, brief, or remarks with regard to the instant matter, other than the original application, which could serve as a basis for a rejection under 35 USC 112, second paragraph. Therefore, withdrawal of the rejections on these grounds is respectfully requested and a notice of allowance is solicited.

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[7] Weiggle et al. 1995 Am J. Physiol. 258 (5 pt 2): H1869-74.
[8] MPEP §2164.03, citing *In re Borkowski*, 422 F.2d 904, 908, 164 USPQ 642, 645 (CCPA 1970).
[9] See *In re Bundy*, 642 F.2d 430, 434, 209 USPQ 48, 51-21 (CCPA 1981) where the court ruled that appellant's disclosure was sufficient to enable one skilled in the art to use the claimed compounds despite the fact that none of the examples of compounds were within the subgenus claimed in the application. The specification did teach, however, that the novel compounds had pharmacological properties and possessed activity similar to known compounds.
[10] *Solomon v. Kimberly-Clark Corp.*, 216 F.3d 1371, 55 USPQ2d 1279 (Fed. Cir. 2000) (Evidence showing that a claim does not correspond in scope with that which the applicant regards as their invention may be found, for example, in briefs or remarks filed by applicant.)
[11] *In re Moore*, 439 F.2d 1232, 169 USPQ 236 (CCPA 1971).

Claims 1, 5, 9-10 stand rejected under 35 USC 112, second paragraph because they include the term "target cell" but do not properly define what a target is. Applicant respectfully traverses this rejection as improper as the language, when considered as a whole, apprises one of ordinary skill in the relevant art of the scope of the claims and serves the notice function required by 35 USC 112, second paragraph. The language provides clear warning to those skilled in the art what constitutes infringement of the patent.

It is well settled that the terms of a claim carry their ordinary meaning, unless it appears that the inventor used them differently. In determining whether a given term is used differently, one must look to the specification.[12] Here the term "target cell" is used in the specification, but not given a special meaning. The term must therefore be given its ordinary meaning. *Merriam-Webster Medical Dictionary, © 2002 Merriam-Webster, Inc.* defines a "target" as "a reference point to shoot at; 'his arrow hit the mark.'" The term "cell," when read in light of the specification, refers to any cell whose growth is sought to be inhibited, such as a cancer cell. This meaning is granted further support by the dependent claims which give examples of target cells (cancer cells).

Given the content of the application, the teachings of the prior art, and the claim interpretation that would be given by one possessing ordinary skill in the pertinent art, it is clear that the term "target cell" refers to a cell whose proliferation is sought to be inhibited. Respectfully, withdrawal of the rejection on these grounds is requested and a notice of allowance solicited.

Claims 4 and 8 stand rejected as lacking an antecedent basis because the independent claims are drawn only to cells. Applicant respectfully traverses this rejection since the scope of the claims would be reasonably ascertainable by those skilled in the art.[13] Without waiving such objection, claims 4 and 8 have been amended to more particularly point out the antecedent basis present in the independent claims.

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[12] See *Gargoyles, Inc. v. United States*, 28 USPQ 2d 1715, 1716–17 (Fed. Cir. 1993)

[13] MPEP §2173.05(e); See also *Ex parte Porter*, 25 USPQ2d 1144, 1145 (Bd. Pat. App. & Inter. 1992)

***Conclusion***

Entry of a Notice of Allowance is solicited. If the Office is not fully persuaded as to the merits of Applicant's position, or if an Examiner's Amendment would place the pending claims in condition for allowance, a telephone call to the undersigned at (727) 507-8558 is requested.

Very respectfully,

SMITH & HOPEN

By: _____

Dated: January 18, 2005

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**CERTIFICATE OF MAILING**
**(37 C.F.R.1.10)**

I HEREBY CERTIFY that this correspondence is being deposited with the United States Postal Service in an envelope as "Express Mail Post Office to Addressee," Express Mail Label No. ED611586866US, addressed to: Mail Stop Amendment, Commission for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on January 18, 2005.

Date: **January 18, 2005**

Shelley Butz